IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

JANET MYERS,	)	
PLAINTIFF,	)	
VS.	)	**CV96-H-465-S**
MEDTRONIC, INC.,	)	
DEFENDANT.	)	

MEMORANDUM OF DECISION

Defendant Medtronic, Inc. ("Medtronic") filed a motion for summary judgment on November 18, 1996. The motion was deemed submitted, without oral argument, to the court for decision as of December 18, 1996. Medtronic submitted a brief in support of its motion and excerpts from the deposition of Dr Vance Plumb, along with its motion on November 18, 1996. The court received no submissions from plaintiff.[1]

Plaintiff commenced this action on January 17, 1996 by filing a complaint in the Circuit Court of Jefferson County, Alabama. Due to continued problems of arterial fibrillation, plaintiff Janet Myers ("plaintiff") had a permanent pacemaker implanted at

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[1] Originally plaintiff was represented by Leigh Ann King and Jonathan Cartee. However, on September 16, 1996 the court granted Leigh Ann King's motion to withdraw as counsel for plaintiff and directed the clerk to treat plaintiff as appearing pro se. The court understands that the motion to withdraw was intended to include Jonathan Cartee and that plaintiff understands that she is now appearing pro se.

University of Alabama at Birmingham's hospital facility on December 27, 1989. See Complaint.

On February 23, 1996 Medtronic removed plaintiff's action to this court on the basis of diversity jurisdiction pursuant to 28 U.S.C. § 1332 and alternatively based on federal question jurisdiction provided by the Medical Device Amendment of 1976 to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321-394.[2] Medtronic filed an answer to the complaint in this court on February 23, 1996.

PLAINTIFF'S ALLEGATIONS:

According to plaintiff, the V lead implanted was defective and caused her to face "an emotionally distressing decision of whether to have the V lead removed because of a significant risk of serious injury or death associated with the removal operation." See Complaint. Plaintiff alleges that on May 29, 1995 she underwent surgery to have the V lead removed "rather than living with the fear of a life threatening rupture." Id. Plaintiff again underwent surgery on June 13, 1995, as a result of pacemaker malfunction secondary to lead displacement.

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[2] Based on the Supreme Court's decision in Medtronic v. Lohr, ___ U.S. __, 116 S.Ct. 2240 (1996), limiting the preemptive scope of the Medical Device Amendments, the existence of the federal question jurisdiction is questionable, but unnecessary for this court to consider due to the uncontested existence of diversity jurisdiction and the absence of any motion to remand by plaintiff.

Plaintiff alleges that Medtronic marketed, supplied or otherwise placed into the stream of commerce the V lead implanted during her surgery that was defective. See Count I of Complaint. In addition to alleging that the V lead was defective, plaintiff alleges that Medtronic defrauded her by misrepresenting (negligently, recklessly or intentionally) to her that the V lead was fit for its intended purposes and would function without defect and/or concealing the fact that the V lead could sustain unexpected fracture which could create life-threatening situations for her. See Counts II through IV of the Complaint.[3]

UNDISPUTED FACTS:

According to plaintiff's physician, Dr. Plumb, plaintiff had a Telectronics 1202 VVI-R pulse generator, with a Medtronic 4004-M bipolar ventricular lead implanted in her body in December 1989. See Dr. Plumb depo. at 19-20; Complaint, Facts at ¶ 3. In 1995, plaintiff's pacemaker device had to be replaced because her pulse generator had reached the end of its life. Id. at 22. The battery in the pulse generator was wearing down. Id. Plaintiff's original pulse generator was extracted and a new ventricular lead

[3] Count V of the Complaint contained no allegations against Medtronic, but rather various allegations against fictitious defendants. Once this case was removed, the fictitious defendants were no longer considered parties and plaintiff failed to amend her complaint to specifically name any additional defendants prior to the expiration of the established period for adding new parties. See March 19, 1996 order.

was implanted, with the old lead being capped. Id. The new lead placed in plaintiff was a CPI Model No. 4162 ventricular lead. Id. at 33.

Dr. Plumb explained that the old lead was capped rather than removed because when a lead has been in the heart for several years it become adherent to the inner surface of the heart, making it difficult and somewhat hazardous to pull it out. Id. at 37. According to Dr. Plumb, to remove such a lead might damage the heart or vascular system. Id. Dr. Plumb testified that generally it is safer to leave a lead in than to remove it. Id. Dr. Plumb explained that the only possible condition created by leaving the old lead in plaintiff, is that it poses a "very, very small risk that it could become a source of infection." Id. at 38.

Plaintiff had to undergo a subsequent surgical procedure in 1995 because the second lead implanted had some minor displacement and failure to capture. Id. at 41. One of Dr. Plumb's partners, Dr. Kay, repositioned the lead. Id. Dr. Plumb testified in his deposition that, in his opinion, the subsequent corrective procedures were not affected by the presence of the old lead being capped. Id.

According to Dr. Plumb, his tests of plaintiff indicated no malfunction in the operation of the lead wire. Id. at 48. Dr. Plumb found no failure in plaintiff's Medtronic lead wire. Id. at 49.

LEGAL ANALYSIS:

Under Fed.R.Civ.P. 56(c), summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion, and identifying those portions of the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact. Celotex, 477 U.S. at 323.

Once the moving party has met his burden, Rule 56(e) requires the nonmoving party to go beyond the pleadings and by his own affidavits, or by the depositions, answers to interrogatories, and admissions of file, designate specific facts showing that there is a genuine issue for trial. Celotex, 477 U.S. at 324. The substantive law will identify which facts are material and which are irrelevant. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. Id. at 249.

The method used by the party moving for summary judgment to discharge its initial burden depends on whether that party bears the burden of proof on the issue at trial. See Fitzpatrick, 2 F.3d at 1115-17 (citing United States v. Four Parcels of Real Property, 941 F.2d 1428 (11th Cir. 1991)(*en banc*)). If the moving party bears the burden of proof at trial, then it can only meet its initial burden on summary judgment by coming forward with positive evidence demonstrating the absence of a genuine issue of material fact; i.e. facts that would entitle it to a directed verdict if not controverted at trial. Fitzpatrick, 2 F.3d at 1115. If the moving party makes such a showing, the burden shifts to the non-moving party to produce significant, probative evidence demonstrating a genuine issue for trial.

If the moving party does not bear the burden of proof at trial, it can satisfy its initial burden on summary judgment in either of two ways. First, the moving party may produce affirmative evidence negating a material fact, thus demonstrating that the non-moving party will be unable to prove its case at trial. If the moving party satisfies its burden using this method, the non-moving party must respond with positive evidence sufficient to resist a motion for directed verdict at trial.

The second method by which the moving party who does not bear the burden of proof at trial can satisfy its initial burden on summary judgment is to affirmatively show the absence of evidence in the record to support a judgment for the non-moving party on the issue in question. This method requires more than a simple statement that the non-moving party cannot meet its burden at trial but does not require evidence negating the

non-movant's claim; it simply requires the movant to point out to the district court that there is an absence of evidence to support the non-moving party's case. Fitzpatrick, 2 F.3d at 1115-16. The affirmative showing may be accomplished by reference to any combination of the following: pleadings; deposition testimony of a party or its witness; affidavits; responses to interrogatories or failure to respond to interrogatories; requests for admission and responses thereto; and other exchanges between the parties that are in the record. See Clark v. Coats & Clark, Inc., 929 F.2d 604 (11th Cir. 1991); see also Celotex, 477 U.S. at 332 (Brennan, J., dissenting). If the movant meets its initial burden by using this second method, the non-moving party may either point out to the court record evidence, overlooked or ignored by the movant, sufficient to withstand a directed verdict, or the non-moving party may come forward with additional evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency.

Medtronic relies exclusively on the deposition of Dr. Plumb in supporting its motion for summary judgment. Defendant argues that it is entitled to summary judgment as a matter of law on all of plaintiff's claims based on the absence of any evidence of: (1) an injury-producing malfunction in the Medtronic V lead implanted in plaintiff; or (2) any defect in the Model 4004 lead implanted in plaintiff.

Essentially, defendant is arguing that plaintiff does not have proper standing to assert a products or fraud claim because she cannot show a legal injury. Plaintiff has presented no evidence that she suffered any physical injury as a result of the implanted Medtronic V lead. As in the Pfizer, Inc. v. Farsian case, 682 So. 2d 405, 407 (Ala. 1996),

plaintiff seeks damages because of the risk that a medical device may one day fail. "Alabama courts have never allowed a recovery based on a product that . . . has been working properly." Pfizer, 682 So. 2d at 407. Plaintiff's fear that the V lead "could fail in the future, is not, without more, a legal injury sufficient to support [her] claim." Id.

The undisputed medical evidence indicates that plaintiff underwent surgery in 1995 to replace the battery in the generator, rather than to replace the V lead. While the plaintiff had a third surgery to repair a V lead, a CPI Model No. 4162 ventricular lead was the one being used at that time, rather than the original Medtronic lead.[4]

In order for plaintiff to defeat summary judgment on her misrepresentation claims, she must establish that the purported representation by Medtronic that the V lead was fit for its intended purposes and would function without defect was false. In other words, proof of "a false representation is an essential element of fraudulent misrepresentation under Alabama law." Bryant v. Southern Energy Homes, Inc., 682 So. 2d 3, 4 (Ala. 1996). Plaintiff has presented no evidence indicating that she has any proof that the Medtronic V lead was not fit for its intended purposes and would not function without defect. Based on Dr. Plumb's testimony it is undisputed that plaintiff's own personal use of the Medtronic V lead between 1989 and when it was capped in 1995

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[4] During the deposition, Dr. Plumb testified that he believes the CPI Model No. 4162 ventricular lead "is a Medtronic lead that CPI had marketing rights to and marketed under their own brand." See Dr. Plumb depo. at 33. The allegations in plaintiff's complaint appear to be addressing the implanting of the pacemaker on December 27, 1989 and alleged representations made at that time rather than any actions prior to her surgery on May 29, 1995, during which the CPI lead was implanted. See Complaint at Facts ¶ 3,6 and Count I ¶ 2.

provided no proof of a failure to meet the intended purpose or function free of any defect. Plaintiff has presented no evidence providing any other sources of evidence to prove this purported false representation. Therefore, defendant's motion for summary judgment is due to be granted and Medtronic is entitled to judgment in its favor on plaintiff's misrepresentation claims as a matter of law.

In order to withstand a motion for summary judgment on her claim of fraud by suppression, "the plaintiff must offer substantial evidence 1) that the defendant had a duty to disclose material facts, 2) that the defendant concealed or failed to disclose those facts, 3) that the concealment induced the plaintiff to act; and 4) that the plaintiff's action resulted in harm to the plaintiff." Hughes v. Hertz Corp., 670 So. 2d 882, 887 (Ala. 1995). There has been no evidence presented to indicate that plaintiff was physically injured as a result of the implantation of the Medtronic's V lead, allegedly after inducement by defendant. Pfizer, Inc. v. Farsian, 682 So. 2d 405, 407 (Ala. 1996), *cert. question conformed*, 97 F.3d 508 (11th Cir. 1996). Therefore, plaintiff has failed to present substantial evidence at the summary judgment stage of any harm to plaintiff as a result of her decision to allow implantation of the V lead in 1989.

Additionally, Medtronic only has a duty to disclose facts that are "material." "A material fact is one which would induce the plaintiff to take action." Lawson v. Cagle, 504 So. 2d 226, 227 (Ala. 1987). Plaintiff alleges in her complaint that Medtronic failed to disclose the fact that the V lead could sustain unexpected fracture which could create life-threatening situations for her. See Complaint at Count IV, ¶ 2. In order for

Medtronic to be legally responsible for a failure to disclose such information, plaintiff must present some evidence that her claim that the V lead may fracture and cause life-threatening situations was in fact true. As stated above, plaintiff has presented no evidence at the summary judgment stage to indicate, even in the slightest manner, that the V lead manufactured by Medtronic and implanted in plaintiff had any likelihood of an unexpected fracture which could lead to a life-threatening situation.

Moreover, such a fact must be shown to be material. In other words, since any implantation of a foreign object in the human body has some physical risks, plaintiff must demonstrate that the likelihood of the fracture of a V lead was significant enough to make the matter material to her decision as to whether to receive such an implantation. Because materiality is generally a question of fact for the jury, the court will base its decision on the total absence of proof by plaintiff as to any harm resulting from the alleged concealment and the lack of any evidence that the proposed fact relating to likelihood of unexpected ruptures in the Medtronic V lead was in fact true. However, the court seriously questions plaintiff's ability to present any evidence of the materiality of such a fact based on the record presently before this court. Based on the foregoing defendant's motion for summary judgment is due to be granted in relation to plaintiff's suppression claims.

"To establish liability under the AEMLD the plaintiff must show (1) the defendant placed a defective product on the market which was unreasonably dangerous and which caused injury or damage; (2) the defendant was engaged in the business of selling the

product; and (3) the product was expected to and did reach the user or consumer without substantial change in condition. Reynolds v. Bridgestone/Firestone, Inc., 989 F.2d 465, 469 (11th Cir. 1993). Plaintiff has the burden of proving that the V lead was in a defective condition when it left Medtronic's control. Key v. Maytag Corp., 671 So. 2d 96, 101 (Ala. Civ. App. 1995). "Alabama defines a defect as 'that which renders a product "unreasonably dangerous" i.e., not fit for its intended purpose.'" Reynolds, 989 F.2d at 469 (*quoting* Casrell v. Altec Industries, Inc., 335 So. 2d 128, 133 (Ala. 1976)). Plaintiff has presented no evidence of how the Medtronic V lead was defective, other than to simply allege that it was "unreasonably dangerous." See Complaint. "Without evidence to support the conclusion that the product was defective and/or unreasonably dangerous when it left the hands of the seller, the burden is not sustained." Key, 671 So.2d at 101 (*quoting* Jordan v. General Motors Corp., 581 So. 2d 835 (Ala. 1991)). As explained above, plaintiff has presented no evidence inferring that the V lead manufactured by Medtronic was not fit for its intended purpose, based on either her personal experience or outside information. Defendant's motion for summary judgment is due to be granted as to plaintiff's product liability claim. In summary, plaintiff fails to state any cause of action for damages, whether it be couched in terms of fraud or product liability law, due to the fact that there is no evidence that her V lead failed, was likely to fail or caused her any physical injury.

DONE this 9th day of January, 1997.

SENIOR JUDGE